

encoded by a nucleic acid wherein said nucleic acid hybridizes at conditions of 2.0 x SSC at 50 °C or higher stringency to a nucleotide sequence of SEQ ID Nos. 1, 3, or 5.

REMARKS

Claims 1, 10, 11, and 58-78 are pending in the application. The Examiner has withdrawn claims 1 and 10 as being drawn to a non-elected invention. Applicants hereby cancel claims 1 and 10. Applicants will now address the concerns raised by the Examiner in the order presented in the Office Action.

1-7. Applicants gratefully acknowledge the withdrawal of the rejections under 35 U.S.C. 112, first paragraph.

8-10. Claims 11, 58-61, 65-67, and 77-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Skolnick, et al. (U.S. Patent No. 5,624,819). Applicants respectfully traverse this rejection.

Skolnick, et al., claims an earliest priority date of March 18, 1994, through a series of abandoned applications, including several continuations-in-part. On page 6, lines 15-17 of our priority document U.S. Application No. 08/154,915, a copy of which is included herewith for the Examiner's convenience, the specification points out that "antibodies directed to p16 can be used to detect virally transformed cells.... The subject invention also relates to agents (e.g., ... antibodies,...) useful in the isolation, diagnostic or therapeutic methods described." On page 25, lines 24-25, the specification of that application states, "The identity between p16INK4 and the CDK4-associated protein p16 was further confirmed using antibodies raised against the GST-p16INK4 fusion protein." Additional support may be found, for example, on page 28, lines 14-23, and elsewhere throughout the specification. Applicants thus submit that the priority date supporting the presently claimed invention established by this filing, November 18, 1993, precedes the filing date of Skolnick et al., and thus disqualifies Skolnick et al. as prior art. Accordingly, Applicants respectfully request withdrawal of this rejection.

11. Applicants gratefully acknowledge the withdrawal of the rejection of claim 65 under 35 U.S.C. 102(b).

12-15. Claims 11 and 58-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skolnick, et al. (U.S. Patent No. 5,624,819). Applicants respectfully traverse this rejection.

As noted above, Applicants submit that their earliest filing supporting the presently claimed invention precedes such disclosure by Skolnick et al., disqualifying Skolnick et al. as prior art. Accordingly, Applicants respectfully request withdrawal of this rejection.

16-18. Claims 65, 77, and 78 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection to the extent it is maintained over the claims as amended.

The Office Action alleges that the specification fails to disclose any common essential features that an amino acid sequence having 80%, 90%, or 95% sequence identity with SEQ ID NOS: 2, 4, and 6 would possess. Applicants respectfully point out that the specification discloses the human sequence for p16, as well as a partial sequence of the mouse p16 (p13.5), as described at page 60, Example 4. In addition, the specification teaches additional members of this family, such as p15, and identifies various characteristics of this novel family of proteins, such as binding to CDK, presence of at least four ankyrin-like repeats, etc. Pages 4 and 5 of the specification set forth amino acid sequences which may be useful in preparing or selecting an amino acid sequence which inhibits activation of a CDK, or a nucleic acid sequence encoding such an amino acid sequence. Additionally, Figure 6 points out a portion of p16 that is highly conserved among related CCR-proteins, such as human p15 and the disclosed mouse fragment of p16, and pages 26-32 of the specification instruct one of skill in the art how to prepare libraries of homologous polypeptides and test them for inhibition of activation of a CDK. Accordingly, it is Applicants' position that the specification provides discloses a representative number of species and have satisfied the written description requirement.

Applicants' position is supported by the Federal Circuit in The Regents of the University of California v. Eli Lilly & Co, 119 F.3d 1559 (Fed. Cir. 1997). In that case, the Federal Circuit, stated that:

a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. This is analogous to enablement of a genus under section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

Here, the specification provides a representative number of species falling within the broad genus and identifies that they have common features, such as having four ankyrin repeats and binding to cyclin-dependent kinases. It has long been known in the art how to prepare an antibody specifically immunoreactive with a particular polypeptide, allowing one of skill in the art to readily identify and prepare antibodies as set forth in claims 65, 77, and 78, using the high level of skill in the art and by following the guidance of the specification as to which amino acid residues are conserved and likely to be important for activity of a particular polypeptide sequence.

Nevertheless, Applicants have amended claim 65 to recite that the antibody binds a naturally occurring CCR polypeptide, wherein the wild-type CCR polypeptide binds a cyclin-dependent kinase. Accordingly, Applicants submit that the claims as amended are fully supported by the specification, and request reconsideration and withdrawal of this rejection.

CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims are now in condition for allowance and early notification to this effect is earnestly solicited. Any questions arising from this submission may be directed to the undersigned at (617) 832-1000.

If there are any other fees due in connection with the filing of this Response, please charge the fees to our **Deposit Account No. 06-1448**. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit account.

Respectfully submitted,
FOLEY, HOAG, & ELIOT



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David P. Halstead, Ph.D.
Reg. No. 44,735
Agent for Applicants

Patent Group
Foley, Hoag & Eliot LLP
One Post Office Square
Boston, MA 02109-2170
Tel: (617) 832-1000
FAX: (617) 832-7000